Tablet

Composition

Each film-coated tablet contains Baricitinib INN 2 mg.

Pharmacology
Baricitinib is a selective & reversible inhibitor of Janus kinase JAK1 and JAK2. In isolated enzyme assays, Baricitinib inhibited the activities of JAK1, JAK2, Tyrosine Kinase 2 & JAK3 with IC50 values of 5.9, 5.7, 53 and > 400 nM respectively. Janus kinases (JAKs) are enzymes that transduce intracellular signals from cell surface receptors for a number of cytokines & growth factors involved in haematopoiesis, inflammation & immune function. Barictinib modulates these signalling pathways by partially inhibiting JAK1 & JAK2 enzymatic activity, thereby reducing the phosphorylation & activation of STATs.

Indication

Indicated for the treatment of adult patients with moderate to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Use of Baricitinib in combination with other JAK inhibitors, biologic DMARDs, or with potent immune suppressants such as Azathioprine & Cyclosporine is not recommended.

Dosage and Administration

Route of Administration : Oral.

1 tablet once daily.

Or as directed by the physician.

Anemia: Avoid initiation or interrupt Baricitinib in patients with hemoglobin less than 8 g/dL

Lymphopenia: Avoid initiation or interrupt Baricitinib in patients with an Absolute Lymphocyte Count less than 500

Neutropenia: Avoid initiation or interrupt Baricitinib in patients with an Absolute Neutrophil Count less than 1000 cells/mm3

Warning & Precautions

Baricitinib should be discontinued in case of severe active infection. Not indicated in Tuberculosis patient. May increase the risk of thrombosis

Gastro-intestinal perforation: Not indicated for patients who are in risk of gastro-intestinal perforation. Patient should not take any live vaccine during treatment with Baricitinib.

Common side effects: Hypersensitivity.

Rare side effects: Respiratory Tract Infections, Nausea, Herpes Simplex & Herpes Zoster.

Use in Pregnancy & Lactation
There are no adequate and well-controlled studies in pregnant women. It is not known whether Baricitinib is excreted in human milk.

Use in Children & Adolescents

Safety and efficacy in children have not been established.

Drug Interactions

With medicine: The recommended dose of Baricitinib in patients taking strong Organic Anion Transporter 3 (OAT3)

inhibitors (e.g., probenecid) is 1 mg once daily.

With food & others: No interaction with food & others.

Overdose

Diarrhoea

Store below 30° C temperature & in dry place, protected from light.

Keep out of the reach of children

Each box contains 1x10 tablets in alu-alu blisters.

* Further information is available on request.

1784/01 2



Manufactured by:

Ohe ACNIE Laboratories Ltd. Dhulivita, Dhamrai, Dhaka, Bangladesh

For Health, Vigour and Happiness